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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,387	10/22/2003	Mark Werner	372768-341524	8628
23911	7590	12/15/2006	EXAMINER	
CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,387

Applicant(s)

WERNER ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 5 and 6 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendments

- 1) Acknowledgment is made of Applicants' amendments filed 08/29/06 and 09/20/06 in response to the non-final Office Action mailed 08/07/06. The amendment filed 09/20/06 is compliant with 37 CFR 1.121.

Status of Claims

- 2) Claims 2-4 have been amended via the amendment filed 09/20/06.
Claims 1-6 are pending in this application.
Claims 1-4 are under examination.

Terminal Disclaimers

- 3) Acknowledgment is made of Applicants' terminal disclaimers filed 09/15/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patents 6,132,733 and 5,453,273.

Prior Citation of Title 35 Sections

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 6) The objection to the abstract made in paragraph 4 of the Office Action mailed 08/07/06 is withdrawn in light of Applicants' amendment to the abstract.
7) The objection to the specification made in paragraph 6 of the Office Action mailed 08/07/06 is withdrawn in light of Applicants' amendment to the specification.

Rejection(s) Withdrawn

- 8) The rejection of claims 1-4 made in paragraph 8 of the Office Action mailed 08/07/06

under the judicially created doctrine of obviousness-type double patenting over claims 5 and 11 of the US patent 6,132,733 ('733), is withdrawn in light of Applicants' submission of the terminal disclaimer disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent 6,132,733.

9) The rejection of claims 1-4 made in paragraph 9 of the Office Action mailed 08/07/06 under the judicially created doctrine of obviousness-type double patenting over claims 1-4 of the US patent US 5,453,273 ('273) in view of Krueger AP (Patent 2,011,225 – Applicants' IDS), is withdrawn in light of Applicants' submission of the terminal disclaimer disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent 5,453,273.

10) The rejection of claims 2-4 made in paragraph 11(b) of the Office Action mailed 08/07/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

11) The rejection of claims 1-4 made in paragraphs 11(a) and 11(c) of the Office Action mailed 08/07/06 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn upon further consideration.

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

12) Claims 1-4 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 and claims 2-4, as amended, include the limitations: 'an effective amount of a homogenized, killed culture'. The generic limitation 'killed ... culture' broadly encompasses a culture killed by various means including formaldehyde-killed, heat-killed, radiation-killed, mechanically killed, etc. The limitation 'an effective amount' would be expected to vary depending on whether the culture is killed by using formaldehyde, heat, radiation, mechanical killing etc. Applicants contend that the instant specification provides a concrete example of at least one effective amount at pages 7-11. The only 'effective amount' of the homogenized, killed cultures of the recited *Microsporum canis*, *Trichosporon mentagrophytes*, and/or *Microsporum*

gypsum that is supported in the instant specification at pages 7-11 is that of formaldehyde-killed cultures of *Microsporum canis*, *Trichosporon mentagrophytes*, and/or *Microsporum gypsum*. This description for the formaldehyde-killed culture species does not provide descriptive support for the generic limitations identified above. Furthermore, 'an effective amount' that is described therein is limited to an amount or concentration that is effective in conferring resistance to ringworm upon administration to a patient. Therefore, the above-identified limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

13) Claims 2-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 2 is vague, indefinite, and appears to lack antecedent basis in the limitation: 'an effective amount of homogenized, killed pure *Microsporum canis* culture wherein each culture is isolated by filtration'. Claim 2 depends from claim 1, which already recites 'an effective amount of homogenized, killed pure *Microsporum canis* culture' wherein the homogenized, killed pure *Microsporum canis* 'culture is isolated by filtration'. Is the 'an effective amount of homogenized, killed pure *Microsporum canis* culture' recited in claim 2 different from the 'an effective amount of homogenized, killed pure *Microsporum canis* culture' that is already recited in the base claim 1, and is this culture in claim 2 isolated for the second time by filtration? Clarification/correction is requested.

(b) Analogous rejection and criticism apply to claims 3 and 4.

Remarks

14) Claims 1-4 stand rejected.

15) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax number (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

16) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

17) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-1600.


S. DEVI, PH.D.
PRIMARY EXAMINER

December, 2006